

APPLICANT FACSIMILE OF FORM PTO-1449

REV 7-90

U.S. DEPARTMENT OF  
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ATTY DOCKET NO

SERIAL NO.

BBI-009C3CN2

09/874389

LIST OF PUBLICATIONS CITED BY APPLICANT  
(Use several sheets if necessary)

APPLICANT

Bujard, Hermann *et al.*

FILING DATE

June 4, 2001

GROUP

1638

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
RRS	A1	4,833,080	05/89	Brent <i>et al.</i>	435	69	
	A2	5,221,778	06/93	Byrne <i>et al.</i>	800	21	
	A3	5,464,758	11/95	Gossen <i>et al.</i>	435	69	
	A4	5,545,808	08/96	Hew <i>et al.</i>	800	3	
RRS	A5	5,595,895	01/97	Miki <i>et al.</i>	435	6	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
RRS	A6	0 332 416	09/89	EP				
	A7	0 455 687 B1	11/91	EP				
	A8	0 455 424 A2	11/91	EP				
	A9	0 494 724 A2	07/92	EP				
	A10	WO 91/13979	09/91	WO				
	A11	WO 91/19796	12/91	WO				
	A12	WO 91/19784	12/91	WO				
	A13	WO 92/11874	07/92	WO				
	A14	WO 92/20808	11/92	WO				
	A15	WO 93/04169	03/93	WO				
	A16	WO 93/23431	11/93	WO				
	A17	WO 94/04672	03/94	WO				
	A18	WO 94/18317	08/94	WO				
	A19	WO 94/29442	12/94	WO				
RRS	A20	WO 96/01313	01/96	WO				

## OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

RRS	A21	Ackland-Berglund, C.E., and Leib, D.A. (1995) "Efficacy of Tetracycline-Controlled Gene Expression Is Influenced by Cell Type" <i>BioTechniques</i> 18(2):196-200.
	A22	Ackland-Berglund, C.E. and Leib, D.A. (1995) "Biofeedback" <i>BioTechniques</i> 19:216-217.
	A23	Agarwal, M.L. <i>et al.</i> (1995) "p53 Controls Both the G <sub>2</sub> /M and the G <sub>1</sub> Cell Cycle Checkpoints and Mediates Reversible Growth Arrest in Human fibroblasts," <i>Proc. Natl. Acad. Sci. USA</i> , 92:pp. 8493-8497.
	A24	Altschmied, L. <i>et al.</i> , (1988) "A threonine to alanine exchange at position 40 of Tet repressor alters the recognition of the sixth base pair of tet operator from GC to AT", <i>The EMBO Journal</i> , vol. 7, No. 12, pp. 4011-4017.
RRS	A25	Baim, S.B., <i>et al.</i> , (1991) "A chimeric mammalian transactivator based on the lac repressor that is regulated by temperature and isopropyl .beta.-D-thiogalactopyranoside", <i>Proceedings of the National Academy of Science</i> , vol. 88, pp. 5072-5076.

Examiner

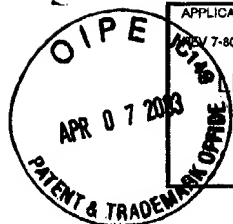
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## OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

R28	B1	Baniahmad, A. et al. (1992) "A Transferable Silencing Domain Is Present In the Thyroid Hormone Receptor, In the v-erbA Oncogene Product and In the Retinoic Acid Receptor" <i>The EMBO Journal</i> 11(3):1015-1023.
	B2	Baumeister, R. et al. (1992) "Contacts Between Tet Repressor And tet Operator Revealed By New Recognition Specificities Of Single Amino Acid Replacement Mutants", <i>Journal Of Molecular Biology</i> , vol. 226, pp. 1257-1270.
	B3	Baumeister, R. et al. (1992) "Functional Roles Of Amino Acid Residues Involved In Forming The $\alpha$ -helix-turn- $\alpha$ -helix operator DNA Binding Motif Of Tet repressor From Tn10", <i>Proteins: Structure, Function, and Genetics</i> , vol. 14(2), pp. 168-177.
	B4	Baumeister, R. et al. (1992) "Tet Repressor Tet Operator Interactions Derived From Mutants With New Recognition Specificities", <i>Structural Tools For The Analysis Of Proten-Nucleic Acid Complexes Advances In Life Sciences</i> , pp. 175-183.
	B5	Bergman, M. et al. "Overexpressed Csk Tyrosine Kinase Is Localized in Focal Adhesions, Causes Reorganization of $\alpha_v\beta_5$ Integrin, and Interferes with HeLa Cell Spreading", <i>Molecular and Cellular Biology</i> , 15, No. 2, pp. 711-722 (1995).
	B6	Boshart, M., et al., (1985) "A Very Strong Enhancer Is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus", <i>Cell</i> , vol. 41, No. 2, pp. 521-530.
	B7	Bradley, A. et al., (1992) "Modifying The Mouse: Design And Desire", <i>Biotechnology</i> , vol. 10, pp. 534-539.
	B8	Bradley, A., (1991) "Modifying the mammalian genome by gene targeting", <i>Current Opinion in Biotechnology</i> , vol. 2, pp. 832-829.
	B9	Brent R. and M. Ptashne (1985) "A Eukaryotic Transcriptional Activator Bearing the DNA Specificity of a Prokaryotic Repressor" <i>Cell</i> 43:729-736.
	B10	Brent, R. and M. Ptashne (1984) "A Bacterial Repressor Protein or a Yeast Transcriptional Terinator Can Block Upstream Activation of A Yeast Gene" <i>Nature</i> 312:612-615.
	B11	Brown, M., et al., (1987) "lac Repressor Can Regulate Expression from a Hybrid SV40 Early Promoter Containing a lac Operator in Animal Cells", <i>Cell</i> , vol. 49, pp. 603-612.
	B12	Buckbinder L. et al. (1994) "Gene Regulation by Temperature-Sensitive p53 Mutants: Identification of p53 response genes" <i>Proc. Natl. Acad. Sci. USA</i> 91:10640-10644.
	B13	Capecchi, M.R., (1989) "Altering the Genome by Homologous Recombination", <i>Science</i> , vol. 244, pp. 1288-1292.
	B14	Cayrol, C. et al. "Identification of Cellular Target Genes of the Epstein-Barr Virus Transactivator Zta: Activation of Transforming Growth Factor $\beta$ h3 (TGF $\beta$ h3) and TGF $\beta$ 1", <i>Journal of Virology</i> , 69, No. 7, p. 4206-4212, (1995).
	B15	Chen, Y.Q. et al. "Tumor Suppression by p21 <sup>WAF1</sup> ", <i>Cancer Research</i> , 55, pp. 4536-4539, (1995).
	B16	Coghlan, A. "Gene dream fades away" <i>New Scientist</i> 148, pp. 14-15, (1995).
	B17	Courey, A.J., and Tjian, R., (1988) "Analysis of Sp1 In Vivo Reveals Multiple Transcriptional Domains, Including a Novel Glutamine-Rich Activation Motif", <i>Cell</i> , vol. 55, pp. 887-898.
R29	B18	Cowell, "Repression versus activation in the control of gene transcription," <i>Trends in Biochemical Sciences</i> , 19:1, 38-42 (1994).

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LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT <b>Bujard, Hermann et al.</b>	
		FILING DATE <b>June 4, 2001</b>	GROUP <b>1638-1632</b>

## OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

RES	C1	Crystal, R.G. "Transfer of Genes to Humans: Early Lessons and Obstacles to Success", <i>Science</i> 270, pp. 404-410 (1995).
	C2	Daddona et al., "Human Adenosine Deaminase." <i>J. Biol. Chem.</i> 259: 12101-12106 (1984).
	C3	Damke, H. et al. "Induction of Mutant Dynamin Specifically Blocks Endocytic Coated Vesicle Formation." <i>The Journal of Cell Biology</i> 127 (4): 915-934.
	C4	Damke, H. et al. "Tightly Regulated and Inducible Expression of Dominant Interfering Dynamin Mutant in Stably Transformed HeLa Cells." <i>Methods in Enzymology</i> 257: 209-220 (1995).
	C5	Degenkolb, J., et al., (1991) "Structural Requirements of Tetracycline-Tet Repressor Interaction: Determination of Equilibrium Binding Constants for Tetracycline Analogs with the Tet Repressor", <i>Antimicrobial Agents and Chemotherapy</i> , vol. 35, No. 8, pp. 1591-1595.
	C6	Deuschle et al., "Tetracycline-reversible silencing of eukaryotic promoters," <i>Mol. Cell. Biol.</i> , 15:4, 1907-1914 (1995).
	C7	Deuschle, U., et al., (1989) "Regulated expression of foreign genes in mammalian cells under the control of coliphage T3 RNA polymerase and lac repressor", <i>Proceedings of the National Academy of Science</i> , vol. 86, pp. 5400-5404.
	C8	Dhawan, J. et al. "Tetracycline-Regulated Gene Expression Following Direct Gene Transfer into Mouse Skeletal Muscle", <i>Somatic Cell and Molecular Genetics</i> , 21, No. 4, pp. 233-240, (1995).
	C9	Ebert, K.M. et al. (1988) "A Moloney MLV-Rat Somatotropin Fusion Gene Produces Biologically Active Somatotropin in a Transgenic Pig." <i>Molecular Endocrinology</i> 2(3): 277-283.
	C10	Efrat, S. et al. "Conditional Transformation of a Pancreatic $\beta$ -Cell Line Derived From Transgenic Mice Expressing A Tetracycline-Regulated Oncogene" <i>Proc. Natl. Acad. Sci. USA</i> , 92, pp. 3576-3580 (1995).
	C11	Epstein-Baak, R., et al., (1992) "Inducible Transformation of Cells from Transgenic Mice Expressing SV40 under Lac Operon Control", <i>Cell Growth &amp; Differentiation</i> , vol. 3, pp. 127-134.
	C12	Fieck, A., et al., (1992) "Modification of the E. Coli Lac Repressor for Expression in Eukaryotic Cells: Effect of Nuclear Signal Sequence on Protein Activity and Nuclear Documentation", <i>Nucleic Acid Research</i> , vol. 20, pp. 1785-1791.
	C13	Figge, J., et al., (1988) "Stringent Regulation of Stably Integrated Chloramphenicol Acetyl Transferase Genes by E. coli lac Repressor in Monkey Cells", <i>Cell</i> , vol. 52, 713-722.
	C14	Fishman G. et al. (1994) "Tetracycline-Regulated Cardiac Gene Expression in Vivo" <i>J. Clin. Invest.</i> 93:1864-1868.
	C15	Fruh, K. et al., "A Viral Inhibitor of Peptide Transporters for Antigen Presentation." <i>Nature</i> 375:415-418 (1995).
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	C17	Furth P. (1994) "Temporal Control of Gene Expression in Transgenic Mice By A Tetracycline-Responsive Promoter" <i>Proc. Natl. Acad. Sci. USA</i> 91:9302-9306.
	C18	Gatz et al., "Stringent repression and homogeneous de-repression by tetracycline of a modified CaMV 35S promoter in intact transgenic tobacco plants," <i>The Plant Journal</i> , 2:3, 397-404 (1992).

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## OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

1638	D1	Gatz, C., and Quail, P.H., (1988) "Tn10-encoded tet repressor can regulate an operator-containing plant promoter", <i>Proceedings of the National Academy of Science</i> , vol. 85, pp. 1394-1397.
	D2	Gatz, C., et al., (1991) "Regulation of a modified CaMV 35S promoter by the Tn 10-encoder Tet receptor in transgenic tobacco", <i>Mol. Gen. Genet.</i> , vol. 227, No. 2, pp. 229-237.
	D3	Gjetting, T. et al. "Regulated Expression of the Retinoblastoma Susceptibility Gene in Mammary Carcinoma Cells Restores Cyclin D1 Expression and G <sub>1</sub> -Phase Control", <i>Biol. Chem. Hoppe-Seyler</i> , 376, pp. 441-446 (1995).
	D4	Gossen et al. (1994) "Inducible Gene Expression Systems For Higher Eukaryotic Cells" <i>Current Opinion in Biotechnology</i> 5:516-520.
	D5	Gossen et al., "Exploiting prokaryotic elements for the control of gene activity in higher eukaryotes," Keystone Symposium on Gene Therapy and Molecular Medicine, Steamboat Springs, Colorado, <i>Journal of Cellular Biochemistry</i> , Supplement 0 (21A), Abstract No. C6-220, 355 (1995).
	D6	Gossen et al., "Transcriptional activation by tetracyclines in mammalian cells," <i>Science</i> , 268:5218, 1766-1769 (1995).
	D7	Gossen M. and B. Hermann (1993) "Anhydrotetracycline, A Novel Effector of Tetracycline Controlled Gene Expression Systems In Eukaryotic Cells" <i>Nucleic Acids Research</i> 21(18):4411-4412.
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	D9	Gossen, M., et al., (1993) "Control of gene activity in higher eukaryotic cells by prokaryotic regulatory elements", <i>TIBS</i> , vol. 18, No. 12, pp. 471-475.
	D10	Gunzburg, W.H. and Salmons, B. "Virus vector design in gene therapy", <i>Molecular Medicine Today</i> 1, pp. 410-417, (1995).
	D11	Haase, S.B. et al. "Transcription Inhibits the Replication of Autonomously Replicating Plasmids in Human Cells", <i>Molecular and Cellular Biology</i> , 14, No. 4, pp. 2516-2524 (1994).
	D12	Hammer, R.E. et al. (1986) "Genetic Engineering of Mammalian Embryos." <i>J. Anim. Sci.</i> 63:269-278.
	D13	Hecht, B., et al., (1993) "Noninducible Tet Repressor Mutations Map from the Operator Motif to the C Terminus", <i>Journal of Bacteriology</i> , vol. 175, No. 4.
	D14	Hennighausen, L. et al. "Conditional Gene Expression in Secretory Tissues and Skin of Transgenic Mice Using the MMTV-LTR and the Tetracycline Responsive System", <i>Journal of Cellular Biochemistry</i> , 59, pp. 463-472, (1995).
	D15	Herschbach B. and A. Johnson (1993) "Transcriptional Repression In Eukaryotes" <i>Annu. Rev. Cell Biol.</i> 9:479-509.
	D16	Hillen, W., and Schollmeier, K., (1983) "Nucleotide sequence of the Tn10 encoded tetracycline resistance gene", <i>Nucleic Acid Research</i> , vol. 11, No. 2, pp. 525-539.
	D17	Hinrichs, W., et al., (1994) "Structure of the Tet Repressor-Tetracycline Complex and Regulation of Antibiotic Resistance", <i>Science</i> , vol. 264, pp. 418-420.
	D18	Houdebine, L.-M. (1994) "Production of Pharmaceutical Proteins From Transgenic Animals", <i>Journal Of Biotechnology</i> vol. 34, pp. 269-287.

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## OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

1205	E1	Howe, J.R. et al. "The Responsiveness of a Tetracycline-Sensitive Expression System Differs in Different Cell Lines", <i>The Journal of Biological Chemistry</i> , 270, No. 23, pp. 14168-14174, (1995).
	E2	Hu, M.C-T and Davidson, N., (1987) "The Inducible lac Operator-Repressor System Is Functional in Mammalian Cells", <i>Cell</i> , vol. 46, pp. 555-566.
	E3	Kappel, C.A., et al., (1992) "Regulating Gene Expression In Transgenic Animals", <i>Current Opinion In Biotechnology</i> , vol. 3, pp. 548-553.
	E4	Krimpenfort, P. et al. "Generation of Transgenic Dairy Cattle Using 'in vitro' Embryo Production." <i>Bio/Technology</i> 9, pp. 844-847 (1991).
	E5	Labow, M.A., et al., (1990) "Conversion of the lac Repressor into an Allosterically Regulated Transcriptional Activator for Mammalian Cells", <i>Molecular and Cellular Biology</i> , vol. 10, No. 7, pp. 3343-3356.
	E6	Liang et al., "Enhanced and switchable expression systems for gene-transfer," Keystone Symposium on Gene Therapy and Molecular Medicine, Steamboat Springs, Colorado, <i>Journal of Cellular Biochemistry</i> , Supplement 0 (21A), Abstract No. C6-220, 379 (1995).
	E7	Licht, J. et al. (1990) "Drosophila Kruppel Protein is a Transcriptional Repressor" <i>Nature</i> 346:76-79.
	E8	Maheswaran, S. et al., "The WT1 Gene Product Stabilizes p53 and Inhibits p53-mediated Apoptosis." <i>Genes &amp; Development</i> 9: 2143-2156 (1995).
	E9	Mansour, S.L., et al., (1988) "Disruption of the proto-oncogene int-2 in mouse embryo-derived stem cells: a general strategy for targeting mutations to non-selectable genes", <i>Nature</i> , vol. 336, pp. 348-352.
	E10	Marshall, E. "Gene Therapy's Growing Pains" <i>Science</i> 269, pp. 1050-1055 (1995).
	E11	Mastrangelo et al "Gene Therapy for Human Cancer: An Essay for Clinicians" <i>Seminars in Oncology</i> 23(1), pp. 4-21 (1996).
	E12	Mendez, B. et al. "Heterogeneity of tetracycline resistance determinants" <i>Plasmid</i> 3 pp. 99-108 (1980).
	E13	Mermod, N., et al., (1989) "The Proline-Rich Transcriptional Activator of CTF/NF-1 Is Distinct from the Replication and DNA Binding Domain", <i>Cell</i> , vol. 58, 741-753.
	E14	Miller, K. et al. "The Function of Inducible Promoter Systems in F9 Embryonal Carcinoma Cells", <i>Experimental Cell Research</i> , 218, pp. 144-150, (1995).
	E15	Muller, G., et al. (1995) "Characterization Of Non-Inducible Tet Repressor Mutants Suggests Conformational Changes Necessary For Induction", <i>Nature Structural Biology</i> , vol. 2(8), pp. 693-703.
	E16	Mullins, L.J. and Mullins, J.J. (1996) "Transgenesis in the Rat and Larger Mammals." <i>J. Clin. Invest.</i> 98(11) Supplement 1996: S37-S40.
	E17	Notarianni, et al., (1990) "Maintenance and differentiation in culture of pluripotential embryonic cell lines from pig blastocysts", <i>Journal of Reproduction and Fertility</i> , Suppl., vol. 41, pp. 51-56.
	E18	Orkin, S. H. and Motulsky, A.G. "Report and recommendations of the panel to assess the NIH investment in research on gene therapy" Dec. 7, 1995.
	E19	Passman, R.S. et al., "Regulated Expression of Foreign Genes In Vivo After Germline Transfer", <i>J. Clin. Invest.</i> , 94, pp. 2421-2425 (1994).

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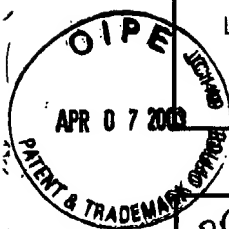
RE9	F1	Pescini R. et al. (1994) "Inducible Inhibition of Eukaryotic Gene Expression" <i>Biochemical and Biophysical Research Communications</i> 202(3):1664-1667.
	F2	Postle, K., et al., (1984) "Nucleotide sequence of the repressor gene of the TN10 tetracycline resistance determinant", <i>Nucleic Acid Research</i> , vol. 12, No. 12, pp. 4849-4863.
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	F4	Renkawitz R. (1990) "Transcriptional Repression In Eukaryotes" <i>TIG</i> 6(6):192-193.
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	F6	Salter, et al. "Transgenic chickens: insertion of retroviral genes into the chicken germ line" <i>Virology</i> 157, pp. 236-240 (1987).
	F7	Sauer, F. and H. Jackle (1993) "Dimerization and the Control of Transcription by Kruppel" <i>Nature</i> 364:454-457.
	F8	Seamark, R.F. (1994) "Progress and Emerging Problems in Livestock Transgenesis: a Summary Perspective." <i>Reprod. Fertil. Dev.</i> 6: 653-657.
	F9	Seipel, K., et al., (1992) "Different activation domains stimulate transcription from remote ('enhancer') and proximal ('promoter') positions", <i>The EMBO Journal</i> , vol. 11, No. 13, pp. 4961-4968.
	F10	Shan, B., et al., "Deregulated Expression of E2F-1 Induces S-Phase Entry and Leads to Apoptosis." <i>Molecular and Cellular Biology</i> 14(12): 8166-8173 (1994).
	F11	Sizemore, C. et al. (1990) "Quantitative Analysis of Tn10 Tet Repressor Binding To A Complete Set Of tet Operator Mutants", <i>Nucleic Acids Research</i> , vol. 18(10), pp. 2875-2880.
	F12	Smithies, O., et al., (1985) "Insertion of DNA sequences into the human chromosomal $\beta$ -globin locus by homologous recombination", <i>Nature</i> , vol. 317, pp. 230-234.
	F13	Sopher, B.L. et al., "Cytotoxicity Mediated By Conditional Expression of a Carboxyl-Terminal Derivative of the $\beta$ -Amyloid Precursor Protein", <i>Molecular Brain Research</i> , 26, pp. 207-217, (1994).
	F14	Strojek, et al. (1988) "The Use Of Transgenic Animal Techniques For Livestock Improvement", <i>Genetic Engineering, Principles and Methods</i> , vol. 10, pp. 221-246.
	F15	Tovar, K., et al., (1988) "Identification and nucleotide sequence of the class E tet regulatory elements and operator and inducer binding of the encoded purified Tet repressor", <i>Mol. Gen. Genet.</i> , vol. 215, pp. 76-80.
	F16	Triezenberg, S.J., et al., (1988) "Functional dissection of VP16, the trans-activator of herpes simplex virus immediate early gene expression", <i>Genes &amp; Development</i> , vol. 2, pp. 718-729.
	F17	Unger, B., et al., (1984) "Nucleotide sequence of the gene, protein purification and characterization of the pSC101-encoded tetracycline resistance-gene-repressor", <i>Gene</i> , vol. 31, pp. 103-108.
	F18	Unger, B., et al., (1984) "Nucleotide sequence of the repressor gene of the RA1 tetracycline resistance determinant: structural and functional comparison with three related Tet repressor genes", <i>Nucleic Acid Research</i> , vol. 12, No. 20, pp. 7693-7703.
	F19	Wall, R.J., (1996) "Transgenic Livestock: Progress and Prospects For The Future" <i>Theriogenology</i> , vol. 45, pp. 57-68.

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